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TITLE: "A Randomized, Controlled Trial of Intranasal Oxytocin as an Adjunct to Behavioral Therapy for Autism Spectrum Disorder"

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14. ABSTRACT The primary objectives of this clinical study are test the hypotheses that (1) cognitive behavioral therapy (CBT) aimed at core social dysfunctions, and (2) oxytocin (OT) administration prior to CBT sessions will each enhance social function in young adults with autism spectrum disorders (ASD), and to examine whether neuroimaging measures of brain function and structure can predict CBT treatment response. To examine these questions, we will recruit and carefully characterize 150 men, ages 18-40, with ASD to participate in this study. Participants will be randomized to receive either social skills training or a stress management/relaxation therapy, and will be randomized to receive either intranasal oxytocin or placebo. Participants and evaluators will be blind to treatment condition. In year 1 of the study, we set up the study framework, including submitting applications for approval from the MGH and MIT Internal Review Boards, and the HRPO. We also received an IND from the FDA for the use of the oxytocin, trained study staff, and began setting up recruitment efforts. The study was approved by the HRPO in April 2014, and we initiated study procedures at this time. To-date, we enrolled 35 participants, have completed neuroimaging with 26 participants, and have randomized 26 participants into treatment. There are no study findings to report at this time, as the study is ongoing.					
15. SUBJECT TERMS autism spectrum disorder, young adult, cognitive-behavioral therapy, social skills training, oxytocin, placebo-controlled, double-blind, clinical trial					
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1. Introduction

The primary objectives of this clinical study are to test the two hypotheses that (1) cognitive behavioral therapy (CBT) aimed at core social dysfunctions and (2) oxytocin (OT) administration prior to CBT sessions will each enhance social function in young adults with autism spectrum disorders (ASD). A third objective is to examine whether neuroimaging measures of brain function and structure can predict CBT treatment responsiveness. To examine these important research questions, we will recruit and carefully characterize 150 men, ages 18-40, with ASD to participate in this study. These will all be high-functioning patients with IQ scores in the average-to-above average range (90 and higher). We will randomly assign ASD volunteers into three groups, with stratification (equation) on age, ASD severity (ADOS score), and non-verbal IQ so that the three groups are equated on those important dimensions. The three groups are: (1) Group 1 (*All Placebo*), who will receive an active placebo behavioral treatment of 12 sessions of relaxation training, and placebo medication; (2) Group 2 (*CBT/placebo*), who will receive the experimental CBT 12-session treatment, and placebo medication; and (3) Group 3 (*CBT/OT*), who will receive the experimental treatment, and OT before 12 sessions of CBT treatment. Volunteers (patients) and evaluators will be blind to condition assignment (double-blind design). We will test the *hypothesis* that CBT helps ASD adults by statistically comparing Groups 1 and 2 on outcome measures (the inclusion of medication placebo equates expectancy effects across the two groups). We will test the *hypothesis* that OT enhances CBT effectiveness in ASD adults by statistically comparing Groups 2 and 3 on outcome measures. We will perform functional (fMRI) and structural (MRI) imaging with all participants prior to treatment, and will examine the relations between measures of brain function and structure with improvements on outcome measures.

2. Keywords

autism spectrum disorder; young adult; male; cognitive-behavioral therapy; social skills training, stress management, oxytocin, placebo-controlled; double-blind; clinical trial

3. Accomplishments

a. What were the major goals of the project?

Specific Aim 1: Recruit and Clinically Characterize 150 Males Ages 18-40 with ASD

Specific Aim 2: Conduct a Double-Blind Placebo-Controlled Clinical Trial of Social Skills Training CBT with Oxytocin Augmentation

Specific Aim 3: Use Neuroimaging to Predict Response to Treatment

b. What was accomplished under these goals?

Task 1. IRB approval

Submit clinical trial description documents to local IRBs and HRPO.

1a. Update consent forms to reflect local IRB and HRPO regulations (months 1) MIT+MGH

1b. Apply for MIT IRB approval (months 1-3) MIT

- We initially submitted the application for IRB approval in May 2013; initial approval was given in October 2013.

- Approval for the continuing review from the MGH IRB was received on September 21st, 2015.

1c. Apply for MGH IRB approval (months 1-3) MGH

1d. Apply for United States Army Medical Research and Materiel Command (USAMRMC) Office of Research Protections (ORP), Human Research Protection Office (HRPO) approval (months 2-5) MGH+MIT

- We received an IND from the FDA on September 19th, 2013 for the use of oxytocin in the study.

- We submitted the protocol to the HRPO upon preliminary approval from MGH and MIT IRB. Approval was received on April 4th, 2014 for the MIT Site and April 7th, 2014 for the MGH Site.

- We created a CT.gov account for the study and have updated this account regularly, as per the CT.gov requirements. This account was most recently updated and verified in September 2015.

- Both MIT and MGH received access to NDAR (National Database for Autism Research) and completed an initial submission July 24th, 2015.

Task 2. Staff recruitment and preparation of testing materials, initial pilot study: This task involves setting up the system for subject recruitment, randomization and tracking, as well as setting up a system for continuously adding assessment results.

- We have trained study clinicians on the CBT therapy protocol, and the independent evaluators on the study measures (training completed in January 2013, with weekly supervision ongoing).
- We have initiated biweekly meetings with MIT and MGH staff to jointly coordinate ongoing steps and topics.
- MIT and MGH staff have completed the work on developing a data entry system that will facilitate cross-site sharing of data.

2a. Prepare stimuli and scanner protocol (months 1-3) MIT

We will create a setup for stimulus presentation using the Psychophysics Toolbox for MATLAB. The setup will include stimulus presentation for functional localizers used in the imaging sessions as well as tests for attention during the pre and post periods. Prepare stimuli and presentation for RMET and Social cooperation task.

Sequences for functional and structural neuroimaging prior to treatment have been tested for study eligibility (all with whole-brain coverage in a higher resolution 32-channel coil):

- o **Resting State:** 2x2x2 mm, TR=1.09s, TE=30 (2x- PA and AP phase encoding)
- o **Structural:** MEMPRAGE: 1x1x1mm, Multi-echo (with possible motion correction)
- o **T2 SPACE:** 1x1x1mm, band width matched to T1-weighted MEMPRAGE
- o **Diffusion weighted:** 5mXXs, 2x2x2 mm, 61 directions, b=1000, 9 b=0 values (2x, PA, AP)
- o **Functional tasks:** 3x3x3mm TR=2.5s, TE=30ms

- **These tasks have been successfully piloted and are functioning as expected**

2b. Setup software for behavioral testing (months 1-3) MGH+MIT

The research coordinator will install the study software on the study purchased laptops.

- **We worked with developers of behavioral tasks to implement several behavioral tasks in the study**
- **The behavioral tasks were first implemented in June 2014 and have been continued as part of the assessment protocols; they are working as expected.**

2c. Run pilot experiments (months 5-7) MGH+MIT

Run the initial pilot study to ensure all components are operational.

- **The imaging protocol was piloted with several participants at MIT and is operating as expected.**

2d. Setup contract with pharmacy to supply drug and placebo after IRB approval.

- **We have been working with the MGH pharmacy, MGH mailroom, and the oxytocin distributor to obtain the oxytocin and placebo for the study. Beginning in January 2014, we successfully ordered and had shipped the oxytocin and placebo from the manufacturer for two orders, set up and implemented the blinding and randomization procedures with the MGH pharmacy, and have been administering the drug/placebo to participants during the treatment phase.**

Task 3. Begin recruitment of 150 subjects (Specific Aim 1,2)

We will start recruiting subjects for the study in an ongoing basis, taking care to balance enrollment subject to characterization by clinical assessment.

3a. Announce study to clinics, referral sources (months 5-34) MGH

- **We created advertising materials including clinician and patient letters, advertisements to be posted on the subway and other public locations, and internet advertisements. We first posted an ad on the local subway in July 2014 and have reposted this ad several times since then. In addition, we have**

posted the ad on Craigslist, the MGH clinical trials website, and the MGH research website. We have also posted paper versions of the ad at local colleges and other public places.

- We have been meeting with local individuals and agencies (e.g., Lurie center, Child Psychiatry Department, and Bressler center) to inform them of our study and facilitate recruitment.
- We have developed and implemented, with the MGH pharmacy, a blocked randomization schedule that takes into account potential confounds such as level of autism severity, IQ, participant age, and current medication status.

Task 4. Subject workflow (months 5-34)

After consenting, all subjects will undergo characterization by the clinician and if admitted to the study will be scheduled for imaging sessions and will be given directives on how to use the software.

4a. Telephone screen MGH

- We developed the telephone screen and received MGH IRB Approval for its use (in October 2013).
- So far, we have screened 58 individuals.

4b. Characterization by clinician (Specific Aim 1) The characterization of subjects will include a formal clinical neurological examination and symptom assessment as described in Specific Aim 1, and a neuroimaging exam (Specific Aim 3). MGH + MIT

- The independent evaluators have been trained (training completed in January 2013).
- To-date, we have consented and conducted baseline characterization with 35 participants and 24 of their parents. Three of these participants were found ineligible at baseline. One participant was withdrawn during treatment after the therapist uncovered that he had psychosis, an exclusion criteria. Four participants dropped out during the study treatment due to scheduling difficulties and/or moving out of state. The remaining 27 participants were found to be eligible for the study and have continued with the study protocol. Eleven participants have completed the study.

4c. Schedule imaging session. MIT

- We have conducted neuroimaging sessions with 27 participants (June 2014 to present). Three individuals did not complete the scanning protocol.
- We have extracted behavioral data, converted dicoms to analysis format, started performing structural image edits for Freesurfer processing stream, and preliminary analysis of functional task activation to verify data quality and expected observations.

4d. Schedule CBT. MGH

Task 5. Perform neuroimaging, pre-treatment assessment and CBT (Specific Aim 2, 3; months 5-34) MGH + MIT. During this phase all subject data are collected. Each subject participates in the study for approximately 60 days.

5a. Collect imaging data during pre-treatment visit. MIT Visit 1 (pre-treatment) consist of structural and functional brain measures requiring 1 hour in the scanner per visit. Diffusion, structural and functional data will be collected.

- Neuroimaging sessions and pre-scanning ADOS-assessments are running smoothly.

5b. Perform CBT for 12 weeks (12 sessions) MGH

- We have randomized 27 subjects to treatment. We expect to randomize 3-4 additional participants into treatment over the next month.

5c. Safety Review

Data collected for the proposed research will be stored in secure physical files, and password protected electronic files. All measures will be taken to protect the identity of participants. The files from this study may be available for review by USAMRAA, the Institutional Review Board (IRB) at MIT and MGH, and by representatives of other governmental agencies as part of their normal duties. All records will be kept in a confidential form. Otherwise, only the members of the research team conducting this study will have access to the study records. Information gained from this study may be used as part of a scientific publication, however, participants will in no way be personally identified. We will keep completely de-identified data wherever possible so that sharing of data is easiest and available for submission into the NDAR.

- We held a DSMB meeting on November 19th, 2014. During this meeting, the DSMB approved study continuation and had no concerns or changes to study procedures.

- The next DSMB meeting is scheduled for November 18th, 2015.

- Both MIT and MGH received NDAR approval in June 2014

Task 6. Analysis of data (Specific Aim 2,3; months 5-34) MIT + MGH

The data will be analyzed at both MIT and MGH. The focus at MIT will be on the analysis of the imaging data, while the focus at MGH will be to analyze the clinical assessment data

6a. Analysis of imaging data

We started analysis of the individual imaging data will using the NiPyPE imaging analysis framework and using tools from well established neuroimaging analysis packages (SPM, FSL and FreeSurfer).

6b. Analysis of behavioral data

When each participant completes the study, the research coordinator will download the participants data from the secure web portal. Research coordinator will transcribe these data into the centralized study database for statistical analysis as described in the full research proposal.

We have started work to extract, visualize, and analyze the clinical and behavioral information stored in the RedCap database.

Task 7. Preparation and publication of results (Specific Aim 3,4; months 34-36)

Once sufficient data has been prediction models will be prepared in order to determine which form of treatment is most effective for a particular case characterization.

7a. Preparation of treatment prediction models MIT

Not yet implemented

7b. Preparation of manuscripts MIT+MGH

Not yet implemented

7c. Submission of curated data into NDAR.

- Initial submission was completed for both MGH and MIT sites in July 2015.

c. What opportunities for training and professional development has the project provided?

Training of technical assistant in preparation of experimental paradigm. This included learning how to morph images using control points, and integrate into a Psychopy stimulus presentation script. Personnel also learned to use Nipype scripts to simplify data conversion and analysis.

Training of three predoctoral psychology interns (Drs. Cooper-Vince, Soto, and Shapero) in the CBT protocol, with opportunities to see at least one case via the study and receive ongoing supervision. Training of two postdoctoral fellows in psychology (Drs. Park and Berman) in the assessment protocols with ongoing practice and supervision.

Training of four bachelor's level research assistants (Ms. Baron, Boudreaux, and Schoeller and Mr. Hoover) on the study measures, including the cognitive assessments and assessment of vital signs.

Research assistants receive ongoing training and supervision, as well as mentorship for pursuing graduate training in clinical psychology.

d. How were the results disseminated to communities of interest?

Both MGH and MIT completed initial submissions to National Database of Autism Research (NDAR) in July 2015.

e. What do you plan to do during the next reporting period to accomplish these goals?

During the next reporting period, we will achieve the following goals:

- Conduct weekly staff meetings with study staff to review study progress, discuss clinical issues, and avoid rater/clinician drift
- Continue study recruitment enrollment of study participants
- Continue baseline assessment and neuroimaging protocols
- Continue randomization to treatment and implement treatment protocols
- Continue week 4, week 8, and week 12 assessment protocols
- Continue data MR data collection
- Continue imaging data analysis on a subject-by-subject level (individual imaging data).
- Continue data analysis of MRI-data on individual level (including, e.g., converting dicoms to analysis format, performing structural image edits for Freesurfer processing stream, analysis of functional task activation, analysis of diffusion-weighted images)
- Start group analyses of neuroimaging data once sample size is sufficient
- Relate behavioral and imaging data (pre-treatment) with treatment outcome measures

4. Impact

a. What was the impact on the development of the principal discipline(s) of the project?

Nothing to Report

b. What was the impact on other disciplines?

Nothing to Report

c. What was the impact on technology transfer?

Nothing to Report

d. What was the impact on society beyond science and technology?

Increased awareness of treatment options for autism currently being evaluated.

5. Changes/Problems

a. Changes in approach and reason for change

We changed our intranasal oxytocin/placebo administration protocol to indicate that a study MD will be present at the first administration of the nasal spray. After the first administration, MDs on study staff will be present in the case of an adverse event, rather than having an MD present at every nasal spray administration. The reason for this change is to decrease the burden of scheduling appointments for study participants, due to the MD availability limitations. This procedure is consistent with other MGH studies using oxytocin. No serious adverse events have been reported from the 26 participants who have administered the oxytocin/placebo nasal spray, to date. This change was approved on September 29th, 2015.

We expanded the age range for recruitment from 18-30 to 18-40. This change was made to increase the size of the population from which we recruit. Individuals up to the age of 40 will not have any negative effects on our data; individuals in the age range of 31-40 years are similar in their treatment needs and should benefit from treatment in the same manner as their younger counterparts. There are also no significant medical or neurological differences in men aged 31 to 40 (compared to those ages 18-30) that would negatively impact data generated from the study or the risks and benefits of their study population. Since this change was made, 9 men between the ages of 31-40 have completed phone screens for the study and 5 of these individuals have been enrolled. This protocol amendment was approved on May 20th, 2015.

b. Actual of anticipated problems or delays and actions or plans to resolve them

Nothing to Report

c. Changes that had a significant impact on expenditures

Nothing to Report

d. Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents

Nothing to Report

e. Significant changes in use or care of human subjects

Nothing to Report

f. Significant changes in use or care of vertebrate animals

N/A

g. Significant changes in use of biohazards and/or select agents

Nothing to Report

6. Products

a. Publications, conference papers, and presentations

i. Journal publications

Nothing to Report

ii. Books of other non-periodical, one-time publications

Nothing to Report

iii. Other publications, conference papers, and presentations

Henin, A (July, 2015). Cognitive Behavior Therapy for Autism Spectrum Disorders. At Autism Spectrum Disorder Across the Lifespan conference, Boston, MA.

b. Website(s) or other Internet site(s)

We initially posted our trial on clinicaltrials.gov in July 2013 and have been updating every six months. The webpage was last verified September 2015.

c. Technologies or techniques

Nothing to Report

d. Inventions, patent applications, and/or licenses

Nothing to Report

e. Other products

- Data or databases - The data from the project are being submitted to the National Database for Autism Research.
- Audio or video products - We have developed a set of novel video stimuli for investigating the emotional and cognitive reactivity of the brain. These will be made available together with the experimental paradigm scripts (see next).
- Software - We have developed a set of scripts for our novel experimental paradigm. In addition, analysis scripts are being created that can be used generally across different projects. These analysis scripts are available as part of the Nipype project. The experimental paradigm scripts will be made available alongside the publication of results.

7. Participants & Other Collaborating Organizations

a. What individuals have worked on the project?

Name:	<i>John D.E. Gabrieli, PhD</i>
Project Role:	<i>Principal Investigator</i>
Researcher Identifier (e.g. ORCID ID):	<i>orcid.org/0000-0003-1158-5692</i>
Nearest person month worked:	<i>1</i>
Contribution to Project:	<i>Dr. Gabrieli has provided overall supervision of the project.</i>
Funding Support:	<i>MIT</i>

Name:	<i>Aude Henin, PhD</i>
Project Role:	<i>Co-Principal Investigator</i>
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	<i>4</i>
Contribution to Project:	<i>Dr. Henin has provided direct supervision and coordination of the project. She has also served as a study therapist.</i>
Funding Support:	<i>MGH</i>

Name:	<i>Satrajit S. Ghosh, PhD</i>
Project Role:	<i>Principal Investigator (subaward)</i>
Researcher Identifier (e.g. ORCID ID):	http://orcid.org/0000-0002-5312-6729
Nearest person month worked:	<i>1</i>
Contribution to Project:	<i>Dr. Ghosh has overseen the execution of the imaging subcomponent, including experimental design, data acquisition, analysis, and submission to NDAR.</i>
Funding Support:	<i>MIT</i>

Name:	<i>Dorit Kliemann, PhD</i>
Project Role:	<i>Postdoctoral Researcher</i>
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	<i>1</i>
Contribution to Project:	<i>Dr. Kliemann has been involved in the execution of the imaging subcomponent, experimental design, data acquisition, analysis and submission</i>
Funding Support:	<i>Feodor Lynen Postdoctoral Fellowship of the Alexander von Humboldt Foundation , MIT</i>

Name:	<i>Dina Hirshfeld-Becker, PhD</i>
Project Role:	<i>Independent Evaluator</i>
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	<i>3</i>
Contribution to Project:	<i>Dr. Hirshfeld-Becker has been an independent evaluator and has evaluated study participants at</i>

	<i>baseline, week 4, week 8, and week 12 assessment periods.</i>
Funding Support:	<i>MGH</i>
Name:	<i>Jamie Micco, PhD</i>
Project Role:	<i>Study Therapist</i>
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	<i>2</i>
Contribution to Project:	<i>Dr. Micco has been treating study participants in both the social skills and stress management treatment conditions.</i>
Funding Support:	<i>MGH</i>

Name:	<i>Susan Sprich, PhD</i>
Project Role:	<i>Study Therapist</i>
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	<i>2</i>
Contribution to Project:	<i>Dr. Sprich has been treating study participants in both the social skills and stress management treatment conditions</i>
Funding Support:	<i>MGH</i>

Name:	<i>Sophie Baron, BA</i>
Project Role:	<i>Clinical Research Coordinator</i>
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	<i>12</i>
Contribution to Project:	<i>Ms. Baron coordinates the study schedule and data.</i>
Funding Support:	<i>MGH</i>

Name:	<i>Christian Hoover</i>
Project Role:	<i>Clinical Research Coordinator</i>
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	<i>4</i>
Contribution to Project:	<i>Mr. Hoover coordinates the study schedule and data entry.</i>
Funding Support:	<i>MGH</i>

Name:	<i>Jennifer Park, Ph.D.</i>
Project Role:	<i>Independent Evaluator</i>
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	<i>2</i>
Contribution to Project:	<i>As an independent evaluator, Dr. Park has administered the study measures to study participants at baseline, week 4, week 8, and week 12 assessment periods.</i>
Funding Support:	<i>MGH</i>

b. Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?

No change.

c. What other organizations were involved as partners?

i. Organization name

Massachusetts Institute of Technology (MIT)

ii. Organization Location

77 Massachusetts Avenue
Cambridge, MA 02139

iii. Partner's contribution to the project

- **Financial support** - Internal support to oversee and execute the project
- **Facilities** - Siemens Magnetom Trio 3 Tesla scanner and High Performance Computing Cluster at the McGovern Institute for Brain Research. The scanning facilities are provided by the Athinoula A Martinos Center for Biomedical Imaging at MIT.
- **Collaboration** - The staff at MIT work closely with the MGH staff on recruitment and scheduling, institutional review board updates, and preparation of project reports.

8. Special Reporting Requirements

a. Collaborative awards

Nothing to Report

b. Quad charts

Nothing to Report

9. Appendices

N/A